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1/77

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Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

28 MAR 2002

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1. Your reference

HP/LP6048011

2. Patent application number

(The Patent Office will fill in this part)

0207416.9

28 MAR 2002

3. Full name, address and postcode of the or of each applicant (underline all surnames)
Patents ADP number (if you know it)

UNIVERSITY COLLEGE LONDON
Gower Street
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WC1E 6BT

30 MAR 02 E707525-3 002823
P02/7700 0.00-0207416.9

798652002

If the applicant is a corporate body, give the country/state of its incorporation

GB

4. Title of the invention

DELIVERY ASSEMBLY FOR USE IN SURGERY

5. Name of your agent (if you have one)

MEWBURN ELLIS

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)

YORK HOUSE
23 KINGSWAY
LONDON
WC2B 6HP

Patents ADP number (if you know it)

109006

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number

Country

Priority application number
(if you know it)

Date of filing
(day / month / year)

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application

Date of filing
(day / month / year)

8. Is a statement of inventorship and of right to grant of a patent required in support of this request?

(Answer "Yes" if:

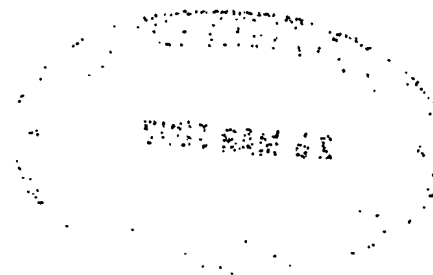
- a) any applicant named in part 3 is not an inventor, or
 - b) there is an inventor who is not named as an applicant, or
 - c) any named applicant is a corporate body.
- See note (d))

YES

Patents Form 1/77

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Continuation sheets of this form 0
Description 7
Claim(s) 2
Abstract 0
Drawing(s) 1 + 1



10. If you are also filing any of the following, state how many against each item

Priority documents 0
Translations of priority documents 0
Statement of inventorship and right to grant of a patent (Patents Form 7/77) 0
Request for preliminary examination and search (Patents Form 9/77) 0
Request for substantive examination (Patents Form 10/77) 0
Any other documents (Please specify) 0

11.

I/We request the grant of a patent on the basis of this application.

Signature

Date

28 March 2002

12. Name and daytime telephone number of person to contact in the United Kingdom

HUGH C. E. PAGET

020 7240 4405

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DELIVERY ASSEMBLY FOR USE IN SURGERY

This invention relates to a delivery assembly for use in surgery, which is applicable in any surgical technique practised on a human or animal body, and in particular in robot-controlled laparoscopic techniques.

Many surgical techniques involve the implantation of a surgically implantable construct, for example a replacement blood vessel in coronary artery bypass surgery. Instead of the large scale opening of the patient's chest to perform heart surgery, laparoscopic techniques have been used recently in which one or more small apertures are opened, and surgery is carried out by means of instruments controlled remotely by the surgeon, together with an observation device such as an endoscope. More recently, robotic procedures have been put into practice in laparoscopic surgery, in which the instruments inside the patient's body are not directly manipulated by the surgeon but are controlled by a computer-operated robotic apparatus which also may present a visual image of the operation site to the surgeon, for example the techniques developed by the companies Intuitive Surgical (known as Da Vinci) and Computer Motion.

In such laparoscopic techniques, it is necessary to deliver a surgically implantable construct to the implantation site, and manipulate it there. Hitherto

this has been done by means of a surgical tool or tools having tweezer-like grippers. An implant construct such as a replacement blood vessel, which may be a blood vessel derived from the patient's own body or may be an artificial construct, is delicate and liable to damage. Its positioning in the body during its implantation, e.g. by suturing, requires care.

The present inventors have noted a need for an improved delivery system for a surgically implantable construct, particularly in laparoscopic surgery, for one or both of the steps of delivering the construct to the implantation site, and maintaining the construct in a desired position or positions at the site during the surgical operation.

According to the present invention there is provided a delivery assembly for use in surgery, comprising a surgically implantable construct, a support on which the construct is removably carried and holding means for releasably holding the construct on said support, wherein the support is selected from:

(i) a tube having an interior surface on which the construct is held, and

(ii) a rod having an exterior surface on which the construct is held.

This delivery assembly provides the advantages of protection of the construct, since it is held on the holding surface of the tube or rod in a controlled manner

and of mounting the construct in a predetermined and known position on the support, which is of value particularly in a robotic technique. The support can be easily moved and positioned and permits the construct to be released when desired. Surgical steps, such as suturing, can be carried out with the construct maintained *in situ* on the support. Techniques are available to the surgeon for suturing the construct, such as a blood vessel tube, even when it is mounted on the holding surface, such as the internal surface of a support in the form of a tube.

To provide a gentle holding of the construct, and easy application of the holding force and its release, the holding means is preferably suction holding means or one or more inflatable members. Suction holding means may comprise one or more apertures in the surface on which the construct is held. Such apertures can connect to conduits within the support. The support surface may have one or more grooves connected to such an aperture or apertures. An inflatable member may form part of the support surface, and is expansible by means of gas pressure supplied through a conduit in the support in order to grip the construct. Alternatively or additionally an inflatable member may be separate from the support, for example a balloon-like member inserted within a tubular implantable construct.

The surgically implantable construct may be of

natural origin, for example a blood vessel derived from the patient, or may be an artificial construct, in particular one containing living cells which requires careful handling. The production of artificial
5 constructs in the form of tubes, possibly containing living cells, is described in our co-pending International Patent Application having the title "Methods and Apparatus for Forming Hardened Tubes and Sheets, filed on 26 March 2002 and claiming priority from
10 UK Patent Applications Nos. 0107549.8, 0120815.6, 0121995.5. The content of the International Patent Application is incorporated herein by reference.

To aid manipulation and positioning of the implantable construct, the support of the delivery
15 assembly may be flexible in a manner such that it maintains a bent shape given to it. Certain plastics materials, e.g. in the form of a rod, hold a bent shape to which they are manipulated. Alternatively the support of the delivery assembly may be in the form of
20 articulatedly connected elements, whose interconnections are adapted to maintain positions to which they are brought.

According to the invention there is also provided a method of surgery wherein a delivery assembly of the
25 invention as described above is employed to bring the surgically implantable construct to its implantation site, and optionally hold it in position at said site

during the performance of one or more surgical steps on it. In robotic surgery, the delivery assembly may be controlled in position by a computer controlled robotic device.

5 Embodiments of the invention will now be described by way of example, with reference to the accompanying drawings, in which:-

 Fig. 1 is a schematic sectional view of a delivery assembly of the invention.

10 Fig. 2 is a schematic sectional view of the second delivery assembly according to the invention.

 Fig. 1 shows an implantable surgical construct in the form of a flexible tube 1 which is to be implanted as a replacement blood vessel in the patient. As mentioned
15 above, the implant may contain or consist of living cells. The tube 1 is carried on the internal cylindrical surface 3 of a rigid cylindrical tubular support 2. The support has a hollow wall 4 and apertures 5 opening at
20 the internal surface, so that by application of reduced pressure inside the wall 4, the implant tube 1 is held by suction against the surface 3. A connection conduit 6 is shown, for the application of the suction pressure. As
25 shown, the implant tube 1 projects slightly from the support 2, so that its end is available for suturing at the surgical site, but this is not necessary. A typical diameter of the tube 1 is 0.5 cm.

 An alternative form of holding means for the

implant tube 1 in the assembly of Fig. 1 is a balloon (not shown) which is inserted inside the tube 1 and inflated to hold the tube 1 against the internal surface 3 of the support.

5 The support 2 can be held at its remote end (not shown) in order to be inserted into the patient through a laparoscopic aperture and can be readily manipulated, e.g. by robotic means. The holding and release of the implant tube 1 by the support is also controlled
10 remotely.

 Fig. 2 shows a second delivery assembly embodying the invention, in which the support for the surgical implant tube 1 is a hollow rigid rod 7 having apertures 5 in its surface for the application of suction pressure to
15 hold the implant tube 1 on the external surface 8 of the rod 7. Although the implant tube 1 is exposed in this embodiment, it is nevertheless protected against kinking or other gross deformation by the supporting rod 7 and can be brought to the surgical site in a controlled
20 manner and maintained accurately in a controlled position at the site, for example while suturing is carried out on it. Instead of the use of suction apertures for holding the implant tube 1 on the support surface 8, the rod may have one or more inflatable structures on its surface
25 which are expanded by pressurised gas supplied along the hollow rod, to grip the implant tube 1. As in the case of the support tube of Fig. 1, the support rod is

suitable to be held and controlled from the exterior of the patient's body, for example by robotic device.

CLAIMS:

1. Delivery assembly for use in surgery, comprising a surgically implantable construct, a support on which said
5 construct is removably carried and holding means for releasably holding said construct on said support, wherein said support is selected from

(i) a tube having an interior surface on which said construct is held, and

10 (ii) a rod having an exterior surface on which said construct is held.

2. Delivery assembly according to claim 1, wherein said holding means is suction holding means comprising
15 one or more apertures in said surface on which said construct is held.

3. Delivery assembly according to claim 1, wherein said holding means comprises one or more inflatable
20 members inflatable to grip said construct.

4. Delivery assembly according to any one of claims 1 to 3, wherein said surgically implantable construct is a tube.

25 5. Delivery assembly according to any one of claims 1 to 4, wherein said surgically implantable construct is of

natural origin.

6. Delivery assembly according to any one of claims 1 to 4, wherein said surgically implantable construct is artificial and contains living cells.

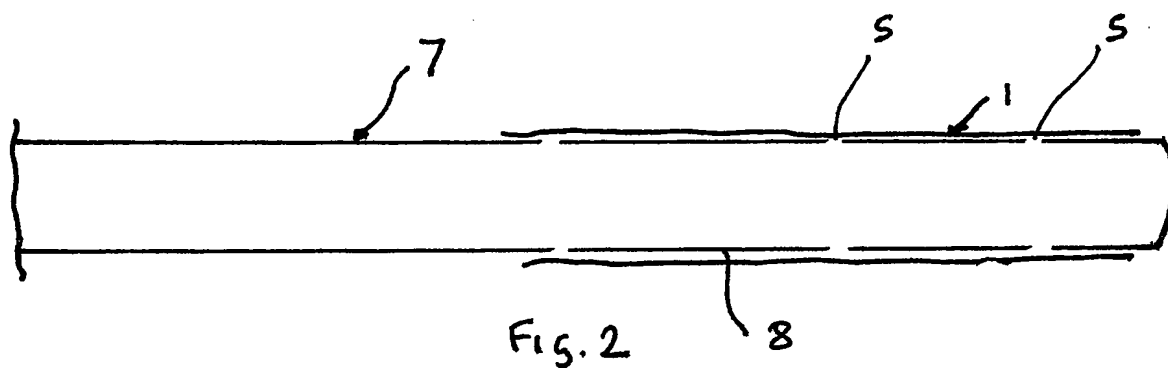
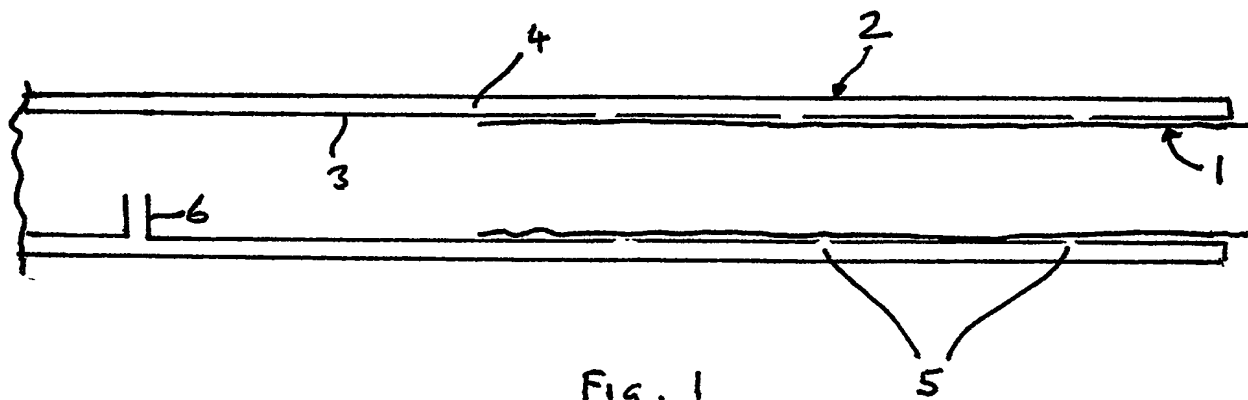
7. Delivery assembly according to any one of claims 1 to 6, wherein said support is flexible and adapted to maintain a bent shape to which it is brought.

10

8. A method of surgery wherein a delivery assembly according to any one of claims 1 to 7 is employed to bring said construct to its implantation site and hold it in position at said site.

15

9. A method according to claim 8, wherein said delivery assembly is controlled in position by a computer-controlled robotic device.



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